



# USP VOLUMETRIC GLASSWARE

USP



USP

Companies that manufacture pharmaceutical products for sale in the United States are audited by US agencies such as the FDA (Food and Drug Administration) and are obligated to meet the requirements of the United States Pharmacopeia (USP) USP.

The current USP states (in Chapter 31) that the Class A error limits outlined in ASTM standards are required for all glass volumetric instruments. These error limits are provided in tables below for volumetric flasks, bulb pipettes, and burettes. For graduated pipettes up to and including the 10 ml size, the error limits are listed in the following text.



### Certificates

USP certificates are enclosed with all LABGLASS pieces that are considered measuring instruments by USP. The certificates state that the Class A error limits correspond to ASTM standards as required.

LABGLASS confirms with the enclosed USP certificates for all USP measuring instruments delivered that the Class A error limits corresponding to the ASTM standards are observed.

### Adjustment and marking

Every piece of volumetric glassware is individually calibrated. For measuring instruments with graduated scales, such as graduated pipettes, burettes and graduated cylinders, flexible screen stencils are used. These stencils can be stretched to match the calibration marks accurately, ensuring that measuring precision is maintained for all intermediate volumes.

Computer-controlled systems within the fully automated production line ensure maximum precision.



### Exceptional Durability

Specific LABGLASS manufacturing methods produce glassware that can withstand extreme high temperatures and thermal shock. LABGLASS glassware can be heated up to 250 degrees in a drying cabinet or sterilizer without any permanent changes to the calibrated measuring capabilities of the glassware.

Specially developed ceramic ink is burned into the glassware at about 540 degrees. The ink will not fade and is acid and alkali resistant.

### Quality management for USP volumetric instruments

The quality management system applied while manufacturing LABGLASS in addition DIN EN ISO 9001 certification requirements include a combination of process monitoring and random checks.

### Reference temperature

The reference temperature of 20°C applies to our volumetric glassware, which are produced according to DIN EN ISO standards. If a volumetric glass calibrated at 20°C is used at 27°C, the volumetric expansion of the instrument results in an additional measurement variation that, at 0.007% (borosilicate glass 3.3) or 0.02% (soda lime glass) is significantly smaller than the error limits for the volumetric glassware. As a result, the reference temperature is of little importance for practical applications. However, if an adjustment or calibration is carried out at a different temperature, the measured values must be corrected accordingly (see DIN EN ISO 4787).

### Calibration Methodology

The calibration of LABGLASS volumetric glassware is performed gravimetrically according to DIN EN ISO 4787 standards. This allows calibration to be completed efficiently while minimizing sources of error.

# Class A volumetric glassware with USP certificate

## TWO TYPES OF USP CERTIFICATES ARE AVAILABLE



### USP batch certificate

The USP batch certificate includes the nominal volume, mean volume, and standard deviation value for the batch along with the certificate issue date and batch number. The batch number is formatted as:

### USP individual certificate

The USP individual certificate includes the standard volume, observed volume, and uncertainty (standard deviation) volume range for the individual glassware piece. Calibration, certificate issue, and suggested recalibration due dates are also included. The individual serial number is formatted as follows:

These certificates are included in the glassware packaging and can also be downloaded from our website.

### BATCH CERTIFICATE

Certificate No. : FL100/05024      Certificate Issue Date : 5-05-2019  
 Calibration Method : Gravimetric Method


PRODUCT DETAIL		
Description of the Item: <u>Vol.Flask 100ml Class A</u>	Cat No.: <u>CH1972E</u>	
Nominal Volume: <u>100ml</u>	Tolerance: <u>± 0.080ml</u>	Compliance: <u>USP/ ISO 1042</u>
Batch No.: <u>FL100 05024</u>	Batch Size: <u>60</u>	

STANDARD EQUIPMENTS USED FOR CALIBRATION		
Name	Weighing Balance	Thermometer
Make	OHAUS	CE
I.D. No.	WB-18	DTM-01
Range	0-210 gm.	-50°C to 200°C
Least Count	0.1 mg	0.1°C




CALIBRATION RESULT		
Nominal Vol.	Mean Vol.	Standard Deviation
100ml	99.962	0.023

**TERMS**

- Results reported are valid under lab conditions at the time of calibration.
- Laboratory Standards are traceable to International standards.

Calibrated by : JNY      Approved by :   
 Quality Manager

Eisco Scientific LLC

ISO/IEC 17025 Accredited Laboratory

### CALIBRATION CERTIFICATE

ULR No. CC273419000000113F

DETAILS	CALIBRATED FOR-
Certificate No. : <u>1900000113</u>	<u>EISCO</u>
Calibration Date: <u>08-07-2019</u>	<u>788 Old Dutch Rd</u>
Certificate Issue Date: <u>09-07-2019</u>	<u>Victor, NY 14564, USA</u>
Suggested Due Date: <u>08-07-2020</u>	

ARTICLE DETAIL	
Description of the Item: <u>Vol. Flask Amber-Class A (CH1974J)</u>	Capacity: <u>1000ml</u> Brand: <u>Eisco Labglass</u>
S. No.: <u>E19-0113</u>	Tolerance: <u>0.30 ml</u> Calibration Slip No.: <u>19011</u>
Compliance: <u>USP/ ISO 1042</u>	Date of Receipt: <u>06-07-2019</u> Visual Inspection: <u>OK</u>

STANDARD EQUIPMENT FOR CALIBRATION					
Name	Make	I.D. No.	Calibrated By	Certificate No.	Validity
Weighing Balance	OHAUS	WB-20	Indian Calibration Services	19700002475	17-03-2020
Thermometer	CE	DTM-01	Belz Calibration Lab	30000272	22-10-2019
Methodology of Calibration: As per calibration Procedure No. QP:121 reference: ISO:4787					

ENVIRONMENTAL CONDITIONS		
Working Temperature (°C) <u>25±0.3</u>	Relative Humidity (m%RH) <u>40-60</u>	Atmospheric Pressure (hPa) <u>978</u>

MECHANICAL CALIBRATION				
CALIBRATION RESULT				
Sr. No.	Reference Temperature	Standard Reading	Observation	Uncertainty at 95% C.L.
1	20°C	1000ml	999.76ml	±0.035ml

**TERMS**

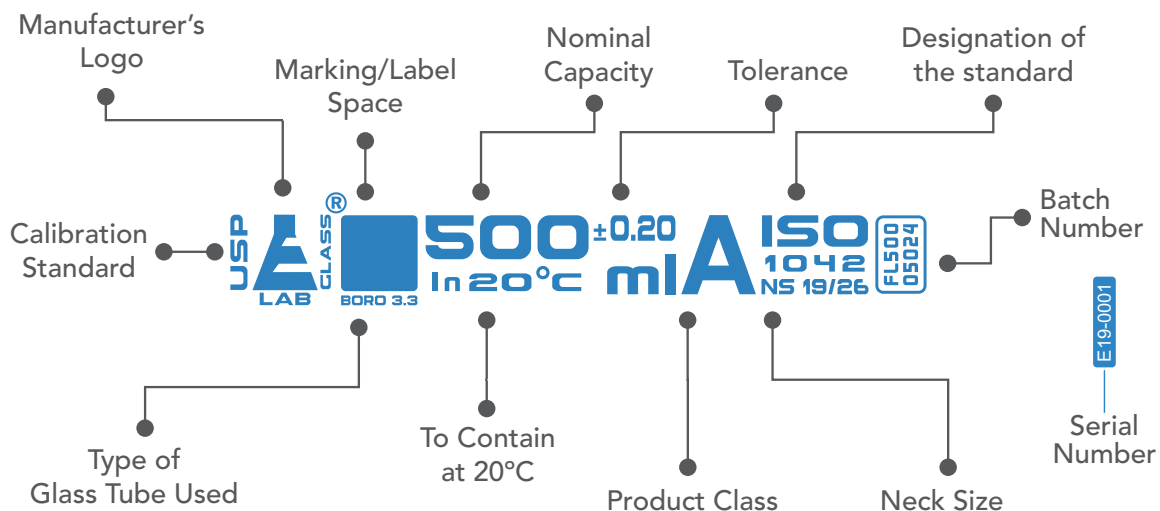
- Above results relate only to the item submitted for calibration.
- This certificate shall not be reproduced, except in full, without the written permission of calibration lab.
- Results reported are valid under the stated conditions of measurement.
- Laboratory Standards are traceable to National Standards.
- The reported uncertainty is at coverage factor k=2 which corresponds to a coverage probability of approximately 95% for a normal distribution. The contribution of uncertainty originating from the standards & balances used, the weighing process and the air buoyancy correction are taken into account.
- Any changes or Correction needed in this certificate will be re-issued as "Amend CAL Certificate" & Certificate will not be issued without written permission of laboratory concerned person.

Calibrated By		Approved By
Kamal	Johny	Manjit Singh
Calibrator		Quality / Technical manager

F-18/03 Page 1 of 1

## Markings on LABGLASS USP Volumetric Glassware

Example- EISCO volumetric flask, USP, Class-A



# Information data – LABGLASS USP volumetric glassware

## Graduated cylinders - glass, Class-A with hexagonal base, USP individual certificate

Code	Capacity (ml)	Sub. Div. (ml)	Tolerance ± ml	Pack Size
CH1930A	5	0.1	0.05	1
CH1930B	10	0.2	0.10	1
CH1930C	25	0.5	0.17	1
CH1930D	50	1.0	0.25	1
CH1930E	100	1.0	0.50	1
CH1930F	250	2.0	1.00	1
CH1930G	500	5.0	2.00	1
CH1930H	1000	10.0	3.00	1
CH1930I	2000	20.0	6.00	1

## Flasks, volumetric Class-A with PP stopper, USP individual certificate

Code	Capacity (ml)	Tolerance ± ml	Socket Size	Pack Size
CH1972A	5	0.020	10/19	1
CH1972B	10	0.020	10/19	1
CH1972B01	20	0.020	10/19	1
CH1972C	25	0.030	10/19	1
CH1972D	50	0.050	12/21	1
CH1972E	100	0.080	14/23	1
CH1972F	200	0.100	14/23	1
CH1972G	250	0.120	14/23	1
CH1972H	500	0.200	16/26	1
CH1972I	1000	0.300	24/29	1
CH1972J	2000	0.500	29/32	1

## Bulb pipettes, 1 mark, Class-AS, USP individual certificate

Code	Capacity (ml)	Tolerance ± ml	Pack Size
CH1992A	0.5	0.006	1
CH1992B	1	0.006	1
CH1992C	2	0.006	1
CH1992D	3	0.01	1
CH1992E	4	0.01	1
CH1992F	5	0.01	1
CH1992G	6	0.01	1
CH1992H	7	0.01	1
CH1992I	8	0.02	1
CH1992J	9	0.02	1
CH1992K	10	0.02	1
CH1992L	15	0.03	1
CH1992M	20	0.03	1
CH1992N	25	0.03	1
CH1992O	30	0.03	1
CH1992P	40	0.05	1
CH1992Q	50	0.05	1
CH1992R	100	0.08	1

## Graduated pipettes, type 2, total delivery, Class-AS, USP individual certificate

Code	Capacity (ml)	Tolerance ± ml	Pack Size
CH1994A	1	0.007	1
CH1994B	2	0.01	1
CH1994C	5	0.02	1
CH1994D	10	0.03	1

## Volumetric flasks, amber glass, Class-A, USP individual certificate

Code	Capacity (ml)	Tolerance ± ml	Socket Size	Pack Size
CH1974A	5	0.020	10/19	1
CH1974B	10	0.020	10/19	1
CH1974C	20	0.020	10/19	1
CH1974D	25	0.030	10/19	1
CH1974E	50	0.050	12/21	1
CH1974F	100	0.080	14/23	1
CH1974G	200	0.100	14/23	1
CH1974H	250	0.120	14/23	1
CH1974I	500	0.200	19/26	1
CH1974J	1000	0.300	24/29	1
CH1974K	2000	0.500	24/29	1

## Burettes - PTFE key stopcock Class-A, USP individual certificate

Code	Capacity (ml)	Sub. Div. (ml)	Tolerance ± ml	Pack Size
CH1914A	10	0.05	0.02	1
CH1914B	25	0.10	0.03	1
CH1914C	50	0.10	0.05	1
CH1914D	100	0.20	0.10	1

## Micro Burette - PTFE key stopcock Class-A, USP individual certificate

Code	Capacity (ml)	Sub. Div. (ml)	Tolerance ± ml	Pack Size
CH1914E	10	0.02	0.02	1

All Class-A volumetric glassware can be USP individual certificate certified. Please contact customer service for more information.  
customer.support@eiscolabs.com

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